

REMARKS

Claims 1- 11, 13 and 14 are pending herein. Claim 1 has been amended to more clearly recite the subject matter of the present invention. Support for the amendment to the claim is found in the specification at pages 3-4. Claims 7 and 10 have been amended to overcome the Examiner's objections as stated on page 2 of the Office Action. No new matter has been added. In light of the foregoing amendments and the following remarks, Applicants request reconsideration and allowance of all pending claims.

Claims 1-6, 8-11 and 13 and 14 were rejected under 35 U.S.C. §103(a) as being unpatentable over Nussinovitch (6,068,867) et al in view of Soon-Shiang et al (5,762,959) and Dorian et al (5,693,514). Applicants traverse this ground of rejection for at least the following reasons.

The present invention, as recited in amended independent claim 1 is for a method of coating a cell comprising the steps of placing the cell in a solution of hydrocolloid; removing the cell from the solution of hydrocolloid; and placing the cell in a cross-linking solution after removing the cell from the solution of hydrocolloid, thereby providing the cell with a thin coating of the hydrocolloid, and storing the cell in solution.

Nussinovitch '867 discloses a method for producing a protective coating for food and/or agricultural product comprising applying to the external surface of said product a gelation solution of the cross-linked hydrocolloid, and, optionally, a solution comprising a gelation inducing agent, wherein at least one of said solutions further comprises at least one natural compound isolated from the surface layers of said product, or at least one compound substantially similar thereto. Column 1, lines 57-65. However, in the method of Nussinovitch

'867, the coating of the agricultural product/food is dried prior to storage, as detailed in Example 1 of that specification at Column 3, lines 48-57.

Coating of fresh garlic heads (bulbs) was performed by immersion of the bulbs in a 2% sodium alginate solution, containing 0.2% (w/w) .beta.-sitosterol, previously dissolved in absolute ethanol. .beta.-sitosterol was purchased from SIGMA. Bulbs were immersed in the solution for 5 to 60 sec; thereafter, excess of the alginate-sterol solution was allowed to drip for about 1 min and the garlic bulbs were then immersed in 2% (w/w) calcium chloride solution for 5 to 60 sec. The wet film was dried either at room temperature, or under a continuous flux of warm air (60.degree. C.) for 5 minutes. After drying bulbs were stored under 25.degree. C. and 70% relative humidity for further evaluation.

Soon-Shiang discloses use of microencapsulation of cells in an alginate. In Soon-Shiang, the interior and exterior of the capsule are comprised of different entities.

Dorian is cited for its disclosure of using non-fibrogenic high mannuronate alginate to coat transplants.

Applicant submits that one of ordinary skill in the art would never have combined the method of Nussinovitch '867 with the disclosure of Soon-Shiang and/or Dorian into the method of the present invention, because there is no hint or suggestion in Nussinovitch '867 that the method of Nussinovitch '867 could be used with live cells. Nussinovitch '867 is directed to agricultural products and food stuffs, the coating should be dried before the food is stored. Accordingly, there is a need to dry the product subsequent to coating it with the hydrocolloid in Nussinovitch '867. In the method of the present invention, there is no drying of the cells prior to storage, because the cells being coated are live, as exemplified in the section entitled Best Mode for Carrying Out the Invention. The method of the present invention is directed to single cell and embryos, unlike the coating process of Nussinovitch '867, which is directed to agricultural products. Consequently, the cells being coated via the method of the present

invention need to be stored properly for growth, that is, they require a nutrient rich medium to promote growth following the coating process. It is well known in the art that animal cells coated with a protective layer that was later dried will perish. Consequently, drying the cells would result in their death. Clearly, the methodology required to retard spoilage is inherently different than the methodology required to sustain growth. Accordingly, one of ordinary skill in the art would not have modified the method of Nussinovitch '867 as shown in Soon Shiang and/or Dorian to result in the method of the present invention.

Furthermore, even if one of ordinary skill in the art were to combine the method of Nussinovitch '867 with Soon-Shiang and/or Dorian, the result would not be the present invention. To begin, the coating of the present invention is homogeneous, whereas the capsules of Soon-Shiang are based on a poly-anion (alginate) polycation reaction, unlike the present invention which involves the reaction of gums with different cross-linking agents. Also, in Dorian, it is disclosed in Examples 2 and 5, that thousands of islets are trapped within a single bead, unlike the present invention, in which single cells are coated. Lastly, the coating of the cells in both Soon-Shiang and Dorian is relatively thick, as compared to the coating of the cells of the present invention. Dorian discloses that the "coating is preferably a thickness of at least 20 micrometers and less than 200 micrometers. This means that if the cell size is of 1 micron diameter, the coating is 20 - 200 times thicker than the cell. In the present invention, the coating is thinner, comprising only a fraction of the cell. Accordingly, Applicant submits that even if one of ordinary skill in the art were to modify the method disclosed in Nussinovitch '867 by combining it with the disclosure of Soon-Shiang and/or Dorian, the result would not be the present invention.

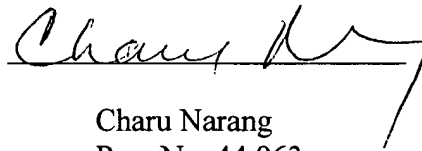
In light of the amendments and the remarks, Applicant requests early and favorable action on the merits.

It is believed that the present amendment is timely. However, if it is determined that this amendment is not timely then this should be considered a petition for an extension of time and the Commissioner for Patents is specifically authorized to charge such fee to Deposit Account No. 50-0518 in the name of Steinberg & Raskin, P.C.

According to currently recommended Patent Office policy, the Examiner is specifically authorized to contact the undersigned in the event that a telephonic interview would advance the prosecution of this application.

Respectfully submitted,

STEINBERG & RASKIN, P.C.


Charu Narang
Reg. No. 44,963

Steinberg & Raskin, P.C.
1140 Avenue of the Americas
New York, New York 10036
(212) 768-3800